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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.   | CONFIRMATION NO. |  |
|---|-------------|----------------------|-----------------------|------------------|--|
| 10/506,448  | 09/01/2004  | Corrado Fogher       | 4161-32               | 8303             |  |
| 29391 7590 11/29/2007<br>BEUSSE WOLTER SANKS MORA & MAIRE, P. A.<br>390 NORTH ORANGE AVENUE |             |                      | EXAMINER              |                  |  |
|   |             |                      | WORLEY, CATHY KINGDON |                  |  |
| SUITE 2500<br>ORLANDO, F  | FL 32801    | ART UNIT             | PAPER NUMBER          |                  |  |
|   |             |                      | 1638                  |                  |  |
|   |             |                      |                       |                  |  |
|   |             |                      | MAIL DATE             | DELIVERY MODE    |  |
|   |             |                      | 11/29/2007            | PAPER            |  |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Advisory Action Before the Filing of an Appeal Brief

| Application No. | Applicant(s)  |  |
|-----------------|---------------|--|
| 10/506,448      | FOGHER ET AL. |  |
| Examiner        | Art Unit      |  |
| Cathy K. Worley | 1638          |  |

|   | Examiner  | AITOIIIT  |   |  |  |  |  |
|---|---|---|---|--|--|--|--|
|   | Cathy K. Worley   | 1638  |   |  |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address   |   |   |   |  |  |  |  |
| THE REPLY FILED <u>08 November 2007</u> FAILS TO PLACE THIS  1.   The reply was filed after a final rejection, but prior to or or   | S APPLICATION IN CONDITION F  | OR ALLOWANCE.                                       | • •                                     |  |  |  |  |
| this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following                     |   |   |   |  |  |  |  |
| time periods:  a) The period for reply expires <u>3</u> months from the mailing date  | e of the final rejection.   |   |   |  |  |  |  |
| b) The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.  Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN |   |   |   |  |  |  |  |
| TWO MONTHS OF THE FINAL REJECTION. See MPEP 7   | 06.07(f).   |   |   |  |  |  |  |
| Extensions of time may be obtained under 37 CFR 1.136(a). The date have been filed is the date for purposes of determining the period of exunder 37 CFR 1.17(a) is calculated from: (1) the expiration date of the set forth in (b) above, if checked. Any reply received by the Office late may reduce any earned patent term adjustment. See 37 CFR 1.704(b) NOTICE OF APPEAL   | tension and the corresponding amount<br>shortened statutory period for reply orig<br>r than three months after the mailing da | of the fee. The approprinally set in the final Offi | iate extension fee ce action; or (2) as |  |  |  |  |
| <ol> <li>The Notice of Appeal was filed on A brief in comp<br/>filing the Notice of Appeal (37 CFR 41.37(a)), or any exte<br/>a Notice of Appeal has been filed, any reply must be filed</li> </ol>   | nsion thereof (37 CFR 41.37(e)), to   | avoid dismissal of th                               |   |  |  |  |  |
| <u>AMENDMENTS</u>   |   | ٠   |   |  |  |  |  |
| <ol> <li>The proposed amendment(s) filed after a final rejection,</li> <li>(a) They raise new issues that would require further co</li> </ol>   | •   |   | ecause                                  |  |  |  |  |
| (b) They raise the issue of new matter (see NOTE below  | ·   | •   |   |  |  |  |  |
| (c) They are not deemed to place the application in be appeal; and/or   | tter form for appeal by materially re   | ducing or simplifying                               | the issues for                          |  |  |  |  |
| (d) ☐ They present additional claims without canceling a  |   | ected claims.                                       | ·                                       |  |  |  |  |
| NOTE: (See 37 CFR 1.116 and 41.33(a)).  |   | mentions Amondmont                                  | (DTOL 224)                              |  |  |  |  |
| <ol> <li>The amendments are not in compliance with 37 CFR 1.1</li> <li>Applicant's reply has overcome the following rejection(s)</li> </ol>   |   | impliant Amendment                                  | (PTOL-324).                             |  |  |  |  |
| <ol> <li>Newly proposed or amended claim(s) would be a<br/>non-allowable claim(s).</li> </ol>   | llowable if submitted in a separate,  | timely filed amendme                                | ent canceling the                       |  |  |  |  |
| 7.  For purposes of appeal, the proposed amendment(s): a) how the new or amended claims would be rejected is pro The status of the claim(s) is (or will be) as follows:   |   | ll be entered and an e                              | explanation of                          |  |  |  |  |
| Claim(s) allowed:   | •   |   |   |  |  |  |  |
| Claim(s) objected to:<br>Claim(s) rejected: <u>52,53,55-62 and 64-69</u> .  | •   |   |   |  |  |  |  |
| Claim(s) withdrawn from consideration: 70-75.   |   |   |   |  |  |  |  |
| <ul> <li>AFFIDAVIT OR OTHER EVIDENCE</li> <li>B. ☐ The affidavit or other evidence filed after a final action, but because applicant failed to provide a showing of good an</li> </ul>  | ut before or on the date of filing a N  | otice of Appeal will no                             | ot be entered                           |  |  |  |  |
| was not earlier presented. See 37 CFR 1.116(e).   |   |   |   |  |  |  |  |
| 9. The affidavit or other evidence filed after the date of filing<br>entered because the affidavit or other evidence failed to<br>showing a good and sufficient reasons why it is necessar  | overcome <u>all</u> rejections under apper<br>y and was not earlier presented. S  | al and/or appellant fa<br>ee 37 CFR 41.33(d)(       | ils to provide a<br>1).                 |  |  |  |  |
| 10. ☐ The affidavit or other evidence is entered. An explanation REQUEST FOR RECONSIDERATION/OTHER  | n of the status of the claims after e   | ntry is below or attach                             | ned.                                    |  |  |  |  |
| 11. ☑ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  See Continuation Sheet.   |   |   |   |  |  |  |  |
| 12. Note the attached Information Disclosure Statement(s).  13. Other:  | (PTO/SB/08) Paper No(s).  |   | ·                                       |  |  |  |  |
| 10. L. Suiei  |   |   |   |  |  |  |  |
|   |   |   |   |  |  |  |  |
|   |   |   |   |  |  |  |  |
|   |   | •   | •                                       |  |  |  |  |

Continuation of 5. Applicant's reply has overcome the following rejection(s): all rejections under 35 USC 112, second paragraph, and all rejections under 35 USC 112, first paragraph, and all claim objections.

Continuation of 11. does NOT place the application in condition for allowance because: The amendments to the claims submitted with the response filed on Nov. 8, 2007, are sufficient to overcome all claim objections and rejections under 35 USC 112. However, the amendments do not overcome the rejection under 35 USC 103(a). The Applicant argues that Radin teaches that the recombinant enzymes were not stable in leaf, stem, flower, and fruit, therefore, as reasonable expectation of success was lacking to use seeds as an effective and stable storage organ (see last paragraph on page 11 of the response). This is not persuasive, however, because Radin does not teach that expression is seeds is unstable, and Whitelam teaches that seeds are a favored site for recombinant protein accumulation in plants (see right column on page 2). The Applicant further argues that one would not have found a reasonable expectation of success because there is no indication in the prior art that the enzyme could be purified in active form from seeds (see first paragraph on page 12 of the response). This is not persuasive, however, because as Whitelam teaches, seeds are a favored site for recombinant protein accumulation in plants, and Whitelam specifically teaches that recombinant therapeutice proteins and enzymes can be produced by bio-farming (see entire article), therefore, one of ordinary skill in the art would expect to succeed in expressing active recombinant lysosomal enzymes in the seeds of transgenic plants.

ANNE MARIE GRUNBERG SUPERVISORY PATENT EXAMINER